



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,679	06/06/2007	Marie-Danielle Nagel	0508-1162	5744

466 7590 06/25/2010  
YOUNG & THOMPSON  
209 Madison Street  
Suite 500  
Alexandria, VA 22314

EXAMINER
----------

ZISKA, SUZANNE E

ART UNIT	PAPER NUMBER
----------	--------------

1619

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

06/25/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/580,679	<b>Applicant(s)</b> NAGEL ET AL.	
	<b>Examiner</b> SUZANNE ZISKA	<b>Art Unit</b> 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 19-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/26/06</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

Claims 1-9 were cancelled by way of preliminary amendment filed 5/26/06. Claims 10-18 were newly added and pending in the application at that time. On 6/6/07, Applicants again cancelled claims 1-9, cancelled claim 10 previously added, added a second set of claims again numbered from 11-18 and added new claim 19.

### ***Claim Objections***

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 11-19 have been renumbered as claims 19-27 and the renumbered claim numbers are used in this Office Action. Correction of the claim numbering is required in reply to this Office Action.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 5/26/06 has been considered by the examiner.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1619

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 23-27 are rejected for failing to distinctly point out and claim the invention.

Claim 23 is generally narrative and indefinite, failing to conform to current U.S. practice. Claim 23 appears to be a literal translation into English from a foreign document. Claim 23 lists approximately 10 different methods of using the bioactive dishes. The claim has been interpreted "as selected from the group consisting of."

Regarding claim 21, the phrase "in particular" renders the claim indefinite for similar reasons.

Regarding claims 24-26, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 27, reciting the phrase "application of" is styled as a "use" claim. Claim 27 provides for the application (use) of the diagnostic method according to claim 26, but, since the claim does not set forth any steps involved in the application method/process, it is unclear what application method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 27 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1619

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Legeay et al (USPN 2002/0193885) [Legeay] and Chabrecek et al (USPN 6,436,481) [Chabrecek].

Legeay discloses implants which are modified on the surface by the creation of polar sites and which are coated with at least one layer of at least one hydrophilic polymer (paragraph [0021]) after creation of the polar sites (paragraph [0043]). Legeay discloses the creation of the polar sites on the surface of the base polymer material corresponds to increasing the proportion of carbonyl, hydroxyl or amine groups and free radicals (paragraph [0034]). Legeay discloses the hydrophilic polymer material can be HPMC (paragraph [0046]) and PVA (paragraph [0049]). Legeay discloses the polar sites are created by plasma treatment, by corona effect discharge or by electromagnetic discharge at atmospheric pressure (paragraph [0063]). Legeay discloses that after the

Art Unit: 1619

creation of the polar sites, a layer of at least one hydrophilic polymer is added to the implant by dipping for example ([0077]) followed by drying ([0078]). Legeay discloses that the base material can be modified on only one of its two surfaces, both surfaces, internal and external (Legeay claims 3 and 4).

Legeay differs from the claims in that the document fails to a culture dish having PVA and CMC as layers on the base material. However, Chabreck cures the deficiency.

Regarding claim 19, Legeay discloses coated implants having at least one hydrophilic polymer layer which can be HPMC and/or PVA. Chabreck discloses coated articles wherein the primary coating comprises a plasma-induced polymer carrying reactive groups, which are reacted with monomeric compounds of semisynthetic or biological origins to provide hybrid type coated articles (secondary coatings) (Abstract). Chabreck discloses that the primary polymeric coating can be PVA (column 12, lines 53-54). Chabreck discloses the hybrid type coating promotes a selective growth of tissue on the outer surface and that a typical secondary coating can be a carbohydrate or a polysaccharide (column 11, lines 1-14).

Chabreck discloses devices having primary and second coatings and which exhibit, inter alia, resistance to mechanical stress, and outstanding thermal, oxidative and hydrolytic stability, desirable permeation characteristics for liquids, gases, ions, nutrients and low molecular weight compounds (column 5, lines 40-51). Chabreck also discloses the device is a coated article having a use as a bioanalytical system, affinity carrier or as permeselective membranes and implants. Chabreck discloses (column 10, lines 6-20) that the coating can provide a substrate for cell attachment and tissue integration.

Both Legeay and Chabreck disclose hydrophilic polymers suitable for both the internal and external layers. It would have been obvious to one of ordinary skill to modify a cell culture dish by adding the first and second layers as taught by both Legeay and Chabreck in view of the teachings of Chabreck that the second coating will provide desired characteristics regarding adherence to the substrate such as reactivity, lubricity, durability, biocompatibility, bioaffinity, bioactivity, and wettability by

Art Unit: 1619

solutions such as human body fluids (column 1, lines 5-18) in order to promote attachment of a particular cell type and obtain a system for bioanalysis as disclosed by Chabreck (claim 19).

Regarding claim 20, Chabreck discloses the substrate is any materially conventionally used for the manufacture of biomedical devices (column 10, lines 35-65, for example), thus rendering obvious a coating on a commercially available petri dish.

Regarding claim 21, Legeay discloses the layer has a thickness of between 10 and 100 nm (paragraph [0088]). It would have been obvious to one of ordinary skill to modify the layer thickness in order to obtain a predetermined thickness, dependent upon the goal at hand.

Regarding claim 22, the combination of Chabreck and Legeay renders obvious the method of making the coated dish. Legeay discloses the polar sites are created by plasma treatment, by corona effect discharge or by electromagnetic discharge at atmospheric pressure (paragraph [0063]). Legeay discloses that after the creation of the polar sites, a layer of at least one hydrophilic polymer is added to the implant by dipping, for example ([0077]), followed by drying ([0078]). Chabreck teaches devices prepared by a similar method having two layers.

All the claimed elements herein are known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

In light of the foregoing discussion, the claimed subject matter would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole is *prima facie* obvious to one of skill in the art at the time the claimed invention was made, as evidenced by the references.

Art Unit: 1619

2. Claims 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Legeay et al (USPN 2002/0193885) [Legeay] and Chabreck et al (USPN 6,436,481) [Chabreck] as applied to claims 19-22 above and further in view of Adair et al (USPN 6,316,215) [Adair].

The teachings of Legeay and Chabreck above are incorporated herein in their entirety.

Legeay and Chabreck differ from the claims in that the documents fail to disclose methods for screening of diseases. However, Adair cures the deficiency.

Adair discloses methods of cancer screening of cells grown in cell culture. It would have been obvious to one of ordinary skill to substitute the culture dishes of Legeay and Chabreck for the culture plates of Adair in view of the teachings of Chabreck, disclosing that the coated article or dish can be used as a bioanalytical system and that the second coating will provide desired characteristics regarding adherence to the substrate such as reactivity, lubricity, durability, biocompatibility, bioaffinity, bioactivity, and wettability by solutions such as human body fluids (column 1, lines 5-18) in order to promote attachment of a particular cell type for further study.

Regarding claims 23-27 claim, claim 23 recites an intended use for the dishes. Chabreck discloses the device is a coated article having used as a bioanalytical system, affinity carrier or permselective membranes and implants. Thus, the use of the dishes in any of the listed methods is rendered obvious by the teachings of Chabreck, disclosing coated devices have a wide range of uses.

Regarding claim 24, use of cell cultures for in vitro study of diseases or conditions is old and well known in the art as evidenced by Adair. Adair contacts cells with compounds and detects morphological changes and proliferative changes (column 4, lines 35-44). Adair discloses that TCPP, for example, will not enter dead cells, thus demonstrating observation of and detection of cellular proliferation and synthesis. Failure to fluoresce indicates a healthy cell culture (column 4, lines 36-44). Further, Chabreck discloses use of the plates as a bioanalytical system and discloses that a wide variety of biomaterials may be used on the surface (column 6, beginning line 6) and that any of the listed biomaterials are suitable for analytical and diagnostic

Art Unit: 1619

techniques. Any of the listed biomaterials may be considered "antiaging" molecules, lacking evidence to the contrary. Further, Applicants' specification includes measurement of cellular proliferation as an indicator of "aging." Chabreck discloses that carbohydrates, oligosaccharides, polysaccharides and peptides and proteins (column 6, beginning line 6) are all suitable for substrate molecules, thus rendering collagen an obvious choice for use in the bioanalytical system for the study of aging.

Regarding claims 25 and 26, Adair discloses observing the cells by microscope in order to study the presence or absence of fluorescence, indicated of their morphology or differentiation. Quantification is disclosed; see figure 3 for example.

Adair discloses a presumptive diagnosis of cancer may be made upon the presence or absence of fluorescing cells (Abstract), thus disclosing the claimed application of the diagnostic method (claim 27).

From the teachings of the references, it is apparent that one of ordinary skill would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole is *prima facie* obvious to one of skill in the art at the time the claimed invention was made, as evidenced by the references.

### **Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE ZISKA whose telephone number is 571-272-8997. The examiner can normally be reached on Monday through Friday 9 AM to 5 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1619

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SUZANNE ZISKA, Ph.D., JD/  
Examiner, Art Unit 1619

/YVONNE L. EYLER/  
Supervisory Patent Examiner, Art  
Unit 1619